IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

VEIN & WELLNESS GROUP, LLC,	*	
Plaintiff,	*	
v.	*	Civil Case No: 1:22-cv-00397-JMC
XAVIER BECERRA, in his official capacity as Secretary of the United States Department for Health and Human Services,	*	
Defendant.	*	

* * * * * * * * * * * *

MEMORANDUM OPINION

Plaintiff Vein and Wellness Group, LLC ("VWG" or "Plaintiff") filed this action for judicial review of a decision by the Secretary of the United States Department of Health and Human Services ("HHS") denying Medicare coverage for 158 vein surgeries performed by Plaintiff during the period of 2014–15. (ECF No. 1). Presently before the Court are the parties' cross-motions for summary judgement (ECF Nos. 18 & 24). Additionally, before the Court is Defendant's Motion for Leave to File Surreply (ECF No. 32). In determining these motions, the Court further considered Defendant's Reply in Further Support of its Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgement (ECF No. 27), Plaintiff's Reply in Support of its Cross-Motion for Summary Judgement (ECF No. 30), and Plaintiff's Opposition to Defendant's Motion for Leave to File Surreply (ECF No. 34). No hearing is necessary. *See* Loc R. 105.6 (D. Md. 2021). For the reasons explained below, Plaintiff's Cross-Motion for Summary Judgment is DENIED, Defendant's Motion for Summary Judgement is

GRANTED, Defendant's Motion for Leave to File Surreply is DENIED[1], and the final administrative decision of the Medicare Appeals Council is AFFIRMED.

I. BACKGROUND

A. Medicare and Medicare Appeals Process and Overview

The Medicare program was established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*, and it is a federal health insurance program that provides subsidized coverage to its recipients. Medicare is administered by the Secretary of the United States Department of Health and Human Services ("HHS"). Medicare Part B, which is the only relevant part of Medicare in this case, is a "supplementary medical insurance program for the aged and disabled" which is financed through monthly fee charges to the beneficiaries and funding from the government. *See* 42 U.S.C. §§ 1395j–1395w–5; 42 C.F.R. Part 410. Congress has excluded from coverage under the Medicare program all items and services "not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1). Congress has delegated to the Secretary the responsibility for deciding whether a particular medical service is medically reasonable and necessary under the Medicare program. 42 U.S.C. § 1395ff(a). Medicare utilizes two types of coverage determinations to determine if medical services are reasonable and necessary: (1) national coverage determinations ("NCD"), 42 C.F.R. §405.1060(a)(1), which are binding decisions issued by the Secretary, and (2) local coverage determinations ("LCD"), 42 U.S.C. §1395ff(2)(b), which are non-binding decisions issued by Medicare Administrative Contractors to guide the application of the "reasonable and necessary"

[1] "The standard for granting leave to file Surreply is whether the party making the motion would be unable to contest matters presented to the court for the first time in the opposing party's reply." *Lewis v. Rumsfeld*, 154 F. Supp. 2d 56, 61 (D.D.C. 2001). Defendant has failed to meet this standard as no new arguments were raised in Plaintiff's Reply in Support of its Cross-Motion for Summary Judgment (ECF No. 30).

standard in particular claim adjudications. After a Medicare Part B provider submits a claim for payment[2], a Medicare contractor makes an initial determination, which is usually approved based upon the providers good faith submission. (ECF No. 18-1, p. 5–6). However, claims that are initially approved are still considered later to ensure accuracy and detect deficiencies in the claim. *Id.* at p. 6. This process of "approve first and examine later" is implemented due to the immense number of Medicare claims submitted each year, thereby promoting administrative efficiency. (ECF No. 18-1, p. 5).

If a provider's claim is denied as not meeting the requirements of Medicare coverage, the provider can follow the five-step appeal process established by the Secretary through regulations. *See* 42 U.S.C. § 405, Subpart I. The first level of appeal is redetermination, which is an examination of the initial claim decision by the Medicare Administrative Contractor. 42 C.F.R. § 405.940 *et seq*. The second level of appeal is reconsideration, which is an independent review performed by a Qualified Independent Contractor ("QIC"). The third level is an ALJ hearing, in which a provider may request a hearing before an administrative law judge. 42 C.F.R. § 405.1000 *et seq*. The fourth level of appeal is Medicare Appeals Council ("MAC") review. 42 C.F.R. § 405.1102. Finally, the fifth level of appeal, and the one this case has reached, is judicial review of a MAC decision. 42 U.S.C. § 1395ff(b)(1); 42 C.F.R. § 405.1136.

B. Statement of Facts

Plaintiff is a limited liability corporation incorporated in Maryland and specializing in vascular treatments. (ECF No. 18-1, p. 10).[3] From April 2014 through December 2015, Plaintiff

[2] Providers submit claims using the Current Procedural Terminology ("CPT") coding system. *See HCPCS – General Information*, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/medicare/coding/medhcpcsgeninfo (last visited Oct. 5, 2022). The CPT code system has been incorporated into the Healthcare Common Procedural Coding System ("HCPSCS") developed by CMS for processing Medicare claims, but these codes do not determine whether a claim is covered under Medicare. (ECF No. 18-1, p. 7).
[3] The Court's pincites to ECF documents are in accordance with the ECF docketing stamps provided at the top of the documents.

performed 158 mechanical occlusion with chemical assistance procedures ("MOCA") on the legs of Medicare beneficiaries to treat their varicose veins. *Id.* at p. 11. In 2014, the MOCA procedure was a new technology for treatment of varicose veins. *Id.* Due to its novelty, the MOCA procedure was not captured by a CPT code through which Plaintiff could properly submit claims for the procedure. *Id.* at p. 12. Plaintiff submitted claims for the relevant MOCA procedures under CPT code 37241. *Id.* The Centers for Medicare and Medicaid Services' ("CMS") contractor initially paid all the Medicare Part B claims at issue within thirty days of submission of the claims, as required by 42 C.F.R. § 405.922. *Id.* In 2016, a Medicare contractor conducted a post-payment review of Plaintiff's claims for 106 beneficiaries because proactive data analysis identified Plaintiff as potentially billing under CPT code 37241. *Id.* at p. 12. Based on this post-payment review, the Medicare contractor found that Medicare had overpaid Plaintiff by approximately $941, 111.96. *Id.* The contractor explained, "Based on Medicare guidelines, the service(s) on the original claim was not considered medically necessary. This decision is based on either the documentation submitted or the failure by the physician/supplier to furnish information that was requested to support the claim." (CAR 25) (quoting contractor's Initial Determination denying the reimbursement claims)). Once the claims were denied, Plaintiff pursued the appeal process.

On redetermination, the Medicare contractor upheld the claim denials because "the information provided did not support the need for this service or item." (*See e.g.*, CAR 337). The contractor explained that MOCA "is not considered effective for large veins greater than 6 mm diameter or for the main saphenous veins." (CAR 338). Pursuant to the adverse redetermination decisions, Plaintiff pursued reconsideration from a QIC and again received an unfavorable decision. (*See e.g.*, CAR 295 ("the medical necessity of the procedures at issue is not demonstrated. . . .In addition to the medical necessity decision, there is also an issue of correct billing . . . .")).

Following an unfavorable reconsideration decision, Plaintiff sought ALJ review. The claims were divided into three groupings for the purposes of the ALJ appeal: Nos. 3-5712041048, Nos. 3-5736021004, and Nos. 3-5712041192. (ECF No. 24-1, pp. 13–14). On August 13, 2021, ALJ Lori L. May issued three decisions in favor of Plaintiff; each decision held that Plaintiff properly billed Medicare for the MOCA procedures and that the procedures were medically reasonable and necessary. (*See e.g.*, CAR 1776). However, the ALJ denied coverage for six claims. (ECF No. 1 ¶ 24). Following these ALJ decisions, CMS submitted a Referral for Own Motion Review of the three ALJ decisions on the grounds that the decisions contained material legal errors. (*See* CAR 23–163). On December 14, 2021, MAC issued a decision upholding the ALJ's denial of six MOCA procedure claims, but the decision reversed the ALJ decision that Medicare covered most of the MOCA procedure claims. (CAR 14–15).

MAC found that the ALJ "did not consider or apply the applicable [Medicare Program Integrity Manual] MPIM provisions for determining the medical reasonableness and necessity of the MOCA procedures." (CAR 16). MAC further found that the records before it did not contain "any published authoritative evidence, or support any general acceptance by the medical community, that the service was safe and effective, not experimental or investigational, and appropriate for the beneficiaries on the dates they received their MOCA procedures. (CAR 17). Overall, MAC concluded that "the ALJ materially erred as a matter of law by not considering or applying the applicable MPIM provisions for determining the medical reasonableness and necessity of the MOCA procedures furnished to the beneficiaries on the dates at issue." (CAR 18).

On February 16, 2022, Plaintiff filed its Complaint in the instant case in accordance with 42 U.S.C. § 1395ff(b)(1)(A). The case is now before this Court for judicial review. In its motion, Defendant argues that summary judgement in its favor should be granted because the Secretary's

final decision, issued by MAC, is legally correct, supported by substantial evidence, and not arbitrary or capricious. (ECF No. 18). Plaintiff argues for summary judgment in its favor on two grounds: (1) the secretary violated his own regulations in rejecting Plaintiff's claim, and (2) the secretary is barred by collateral estoppel from denying coverage. (ECF No. 24-1).

II. STANDARD OF REVIEW

This Court is obligated to review the Secretary's final decision pursuant to 42 U.S.C. § 1395ff(b)(1)(A), which specifically incorporates 42 U.S.C. § 405(g). The Court's review of the "Secretary's final decision in this case . . . is to be based solely on the administrative record, and the Secretary's findings of fact, if supported by substantial evidence, shall be conclusive." *MacKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 346 (4th Cir. 2007) (citing 42 U.S.C. § 1395ff(b)(1)(A)). This Court has the power only to "affirm[], modify[], or revers[e] the decision of the [Secretary] . . . ." 42 U.S.C. § 405(g).

As indicated by both parties, this Court's review, including considerations of issues of law, is further governed by the Administrative Procedure Act ("APA"). The Court will uphold final agency action so long as it is not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[,] . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right[,] . . . without observance of procedure required by law[,] . . . [or] unsupported by substantial evidence . . . ." 5 U.S.C. § 706(2)(A), (C), (D), & (E). "The foregoing statutory criteria render [this Court's] oversight 'highly deferential, with a presumption in favor of finding the agency action valid,' yet the arbitrary-and-capricious standard does not 'reduce judicial review to a rubber stamp of agency action.'" *Friends of Back Bay v. U.S. Army Corps of Eng'rs*, 681 F.3d 581, 587 (4th Cir. 2012) (citations omitted). The United States Supreme Court has explained:

> The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained. Judicial review under that standard is

> deferential, and a court may not substitute its own policy judgment for that of the agency. A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision.

Fed. Commc'ns Comm'n v. Prometheus Radio Project, 141 S. Ct. 1150, 1158 (2021) (other citations omitted). The Court will find action of an agency arbitrary and capricious "if the agency relies on factors that Congress did not intend for it to consider, . . . explains its decision in a manner contrary to the evidence before it, or reaches a decision that is so implausible that it cannot be ascribed to a difference in view." *Ergon-W. Va., Inc. v. U.S. Env't Prot. Agency*, 896 F.3d 600, 609 (4th Cir. 2018).

Summary judgment is warranted when there is no dispute as to material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Because all the facts are set forth in the Certified Administrative Record when a case is brought under the Medicare Act and the APA, there are no factual disputes to resolve, and the entire case is a question of law. *See Hyatt v. U.S. Pat. and Trademark Off.*, 146 F. Supp. 3d 771, 780 (E.D. Va. 2015). "[R]eview is limited to the administrative record and resolution does not require fact finding on behalf of [the] court. . . . [S]ummary judgment serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA." *Id.*

III. ANALYSIS

A. Collateral Estoppel Does Not Bar the Secretary's Decision in This Case.

This Court is not convinced that collateral estoppel applies to bar the Secretary's decision in this case. "Under collateral estoppel, once a court has decided an issue of fact or law necessary to its judgment, that decision may preclude relitigation of the issue in a suit on a different cause of action involving a party to the first case." *Allen v. McCurry*, 449 U.S. 90, 94 (1980) (citing *Montana v. United States*, 440 U.S. 147, 153 (1979)). "Collateral estoppel has the dual purpose of

protecting litigants from the burden of relitigating an identical issue with the same party or his privy and of promoting judicial economy by preventing needless litigation." *Parklane Hosier Co., Inc. v. Shore*, 439 U.S. 322, 326 (1979) (citing *Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 328–29 (1971)). "The Supreme Court has considered how some administrative and state agency decisions are given preclusive effect in Article III courts." *Christenson v. Azar*, No. 20-C-194, 2020 WL 3642315 (E.D. Wis. Jul. 6, 2020), *reconsideration denied sub nom. Prosser v. Azar*, No. 20-C-194, 2020 WL 6266051 (E.D. Wis. Sept. 24, 2020). Plaintiff cites to and quotes *Astoria*:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata* to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 107–08 (1991) (internal citations and quotations omitted). Plaintiff further relies on *Astoria*'s assertion that "where a common-law principle is well established, as are the rules of preclusion . . . the courts may take it as a given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident." *Id.* at 108. As indicated by Defendant, only one court has squarely addressed the issue of whether collateral estoppel will apply to subsequent Medicare

coverage determinations.[4] (ECF No. 21, p. 7). In *Christenson*, the United States District Court for the Eastern District of Wisconsin, after considering the issue twice, held that collateral estoppel should not apply in the context of Medicare appeals; for the forthcoming reasons, this Court agrees. *See Christenson*, No. 20-C-194, 2020 WL 3642315.

In *Christenson*, plaintiffs filed an action for judicial review of a decision by the Secretary of HHS pursuant to 42 U.S.C. 405(g) and 42 U.S.C. § 1395ff. *Id.* at 1. The parties in *Christenson*, just like here, filed cross-motions for summary judgment, disputing whether the doctrine of collateral estoppel should preclude the Secretary from denying Medicare coverage to plaintiffs based on ALJ decisions. *Id.* Identical to the plaintiff in *Christenson*, Plaintiff here relies on the above-quoted passage from *Astoria* regarding the "long favored application of the common-law doctrines of collateral estoppel . . . to those determinations of administrative bodies that have attained finality." *Id.* at 4 (citing *Astoria*, 501 U.S. at 107–08). However, while the court in *Christenson* found that this excerpt from *Astoria* provides insight regarding the practical benefits of common law doctrines, the court found other passages more relevant to this particular issue. *Christenson*, No. 20-C-194, 2020 WL 3642315, at 4. "Courts do not, of course, have free rein to impose rules of preclusion, as a matter of policy, when the interpretation of a statute is at hand. In this context, the question is not whether administrative estoppel is wise but whether it is intended by the legislature." *Id.* (quoting *Astoria*, 501 U.S. at 108) (internal quotations omitted). The

[4] Plaintiff and Defendant seemingly misunderstand the history of *Christenson*. The United States District Court for the Eastern District of Wisconsin denied the plaintiff's motion for summary judgment on July 6, 2020, on the grounds that collateral estoppel does not apply in Medicare appeals cases. *Prosser v. Azar*, No. 20-C-194, 2020 WL 6266040, at 1 (E.D. Wis. Oct. 21, 2020), *aff'd sub nom. Prosser v. Becerra*, 2 F.4th 708 (7th Cir. 2021). On September 24, 2020, the court, on reconsideration, again considered the issue of collateral estoppel in the context of a Medicare appeal, and the court again rejected its application. *Id.* at 1. Subsequently, the Secretary filed a motion for summary judgment on the ground that plaintiff lacked standing, and the court granted that motion. *Id.* The granting of the Secretary's motion for summary judgment was affirmed by the United States Court of Appeals, Seventh Circuit. *Prosser v. Becerra*, 2 F.4th 708 (7th Cir. 2021). Although Plaintiff is correct to point out that the 7th Circuit did not affirm the portion of the previous decisions pertaining to collateral estoppel, Plaintiff has failed to diminish the precedential value that this Court believes *Christenson* still provides.

Christenson court recognized that *Astoria* found against the application of estoppel: "We reach the same result here, for the Age Act, too, carries an implication that the federal courts should recognize no preclusion by state administrative findings with respect to age-discrimination claims. While the statute *contains no express* delimitation of the respect owed to state agency findings, its filing requirements make clear that collateral estoppel is not to apply." *Christenson*, No. 20-C-194, 2020 WL 3642315, at 4 (quoting *Astoria*, 501 U.S. at 110–11) (emphasis added).

Christenson recognized that there exists no "statutory language that resolves the question, showing that Congress explicitly addressed principles of issue preclusion." *Christenson*, No. 20-C-194, 2020 WL 3642315, at 4. However, "Congress did entrust the Secretary . . . to promulgate regulations to make initial determinations with respect to whether an individual is entitled to benefits and the amount of such benefits." *Id.* (quoting 42 U.S.C. §§ 1395ff(a)(1); 1395hh) (internal quotations omitted). "The statute also makes clear that Medicare coverage determinations are subject to review in federal district court after they proceed through an internal administrative review. *Christenson*, No. 20-C-194, 2020 WL 3642315, at 4 (citing *Heckler v. Ringer*, 466 U.S. 602, 606 (1984) ("Pursuant to her rulemaking authority, the Secretary has provided that a 'final decision' is rendered on a Medicare claim only after the claimant has pressed the claim through all designated levels of administrative review.")). This Court agrees with *Christenson* that "[w]hile not addressing collateral estoppel, Congress clearly entrusted the Secretary with overseeing multiple levels of administrative review that must be exhausted before judicial review by an Article III court is appropriate." *Christenson*, No. 20-C-194, 2020 WL 3642315, at 4.

The court in *Christenson* acknowledged the absence of statutory language speaking directly to the doctrine of collateral estoppel, so it turned to relevant HHS guidance. *See id.* at 5. There, as here, the Secretary argued that its regulation precluded the application of collateral estoppel to ALJ

decisions. *Id.* The Secretary directs this Court to 42 C.F.R. § 401.109, which provides, "The Chair of the Department of Health and Human Services Departmental Appeals Board (DAB Chair) may designate a final decision of the Secretary issued by the Medicare Appeals Council . . . as precedential . . . ." *Id.* (quoting 42 C.F.R. § 401.109(a)). "It follows that, as the Secretary argues, ALJ decisions are not binding on another ALJ as only Council-level decisions can carry binding effect. *Id.* (citing *W. Tex. LTC Partners, Inc. Dep't of Health & Human Servs.*, 843 F.3d 1043, 1047 (5th Cir. 2016) ("[P]rior ALJ decisions are not binding on the DAB or other ALJs."); *Britthaven of Chapel Hill*, DAB No. 2284 (2009) (H.H.S. Nov. 17, 2009) ("We note at the outset that neither the Board nor other ALJs are bound by an ALJ decision.")) (other citations omitted).

The Medicare administrative review structure is not compatible with collateral estoppel. *Christenson*, No. 20-C-194, 2020 WL 3642315, at 5. "The Restatement of Judgement informs that 'final judgment,' with respect to collateral estoppel, is understood to mean any prior adjudication of an issue in another action that is determined to be sufficiently firm to be accorded conclusive effect." *Id.* (citations and internal quotations omitted). "It is difficult to conclude that, within the multi-layer scheme of internal claim review, administered by the Secretary, the early stage of ALJ review is the point at which an issue becomes final for purposes of collateral estoppel." *Id.* at 6. The Secretary's regulations defining "precedential effect . . . suggests that the decision at the ALJ level is less deliberately adequate than one rendered by a federal district or state court." *Id.* The Defendant's application of the precedential effect regulation also finds support in the Restatement:

> [a]n adjudicative determination of an issue by an administrative tribunal does not preclude relitigation of that issue in another tribunal if according preclusive effect to determination of the issue would be incompatible with a legislative policy that: (a) The determination of the tribunal adjudicating the issue is not to be accorded conclusive effect in subsequent proceedings."

Id. (citation and quotations omitted). The Secretary's regulations regarding precedential effect represents "a policy decision that Congress has delegated to the Secretary to implement in administering Medicare's internal review process." *Id.*

Furthermore, regarding finality, the Secretary did not participate in the three ALJ hearings upon which Plaintiff relies. *Id.* at 7. Pursuant to 42 C.F.R. § 405.1012(a), the Secretary may elect to be a party to a hearing. Here, the Secretary argues that "it is impracticable for the Secretary to litigate over 400,000 Medicare claims appeals filed each year at the ALJ level." (ECF No. 27, p. 20–21) (citing 42 C.F.R. §§ 405.1010(a), 405.1012)) (other citations omitted). If a party does not become a party to an ALJ hearing, it cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). This means that the Secretary would need to litigate every ALJ hearing to have the right to appeal any decisions favorable to the provider or beneficiary, and this Court is not prepared to mandate this impossibility. *See Christenson*, No. 20-C-194, 2020 WL 3642315, at 7 ("[T]he court accepts that even several thousand beneficiary appeals filed annually makes it virtually impossible for the Secretary to be represented at every ALJ-level hearing."). Additionally, since the ALJ is the Secretary's assigned adjudicator and not the Secretary's representative, "the court cannot conclude that an issue was meaningfully resolved between parties [since] the agency d[id] not appear on its own accord." *Id.* Congress entrusted the Secretary with the discretion necessary to oversee the administration of the internal review regarding Medicare determinations, and the Secretary's "regulations determining when decisions are binding on the same parties in the future are not an unreasonable abuse of its discretion to carry out this task." *Id.*

Plaintiff contends that the caselaw cited indicates that the Court should not look to the Secretary's regulations in determining Congressional intent regarding collateral estoppel in Medicare appeals cases. (ECF No. 30, p. 5). However, the *Christenson* opinion was again

considered by the United States District Court for the Eastern District of Wisconsin on a motion for reconsideration. *Prosser v. Azar*, No. 20-C-194, 2020 WL 6266051 (E.D. Wis. Sept. 24, 2020). In that motion, the plaintiff argued that it was manifest error for the court to review Medicare regulations after the court had already determined that Congress did not "speak directly" on the issue of collateral estoppel with respect to Medicare. *Id.* at 1. However, Congress may "delegate administrative authority directly or indirectly. *Id. Astoria* considered this issue, as well, explaining that "the interpretative presumption that collateral estoppel applies on the basis of common law principles is *not*, however, *one that entails a requirement of clear statement*, to the effect that Congress must state precisely any intention to overcome the presumption's application to a given statutory scheme." *Id.* (quoting *Astoria*, 501 U.S. at 108) (emphasis added and internal quotations omitted). Furthermore, "[a]lthough administrative estoppel is favored as a matter of general policy, its suitability may vary according to the specific context of the rights at stake, the power of the agency, and the relative adequacy of agency procedures. *Prosser*, No. 20-C-194, 2020 WL 6266051, at 1 (quoting *Astoria*, 501 U.S. at 109–10); *see also Walker v. Selig*, No. 2:15-cv-00166 KGB, 2015 WL 12683818, at *15 (E.D. Ark. Oct. 30, 2015) ("Even if the elements of preclusion could be met, . . . this [c]ourt would decide not to apply preclusion or administrative estoppel based on the specific context of the rights at stake here, [and] the power of the agency and the interest of the agency in reaching the decision it reached . . . .).

"Medicare's labyrinth review system and myriad regulations suggest an administrative scheme unlike others." *Christenson*, No. 20-C-194, 2020 WL 3642315, at 7. Just like the only other federal court in this country concluded, this Court also concludes that collateral estoppel is inapplicable in the Medicare appeal context.

B. Defendant Did Not Violate Its Own Regulations in Rejecting the Claims.

Plaintiff contends that the Secretary violated his own regulations in rejecting Plaintiff's claims. (ECF No. 24-1, p. 17). Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), this Courts review is limited to the Secretary's final decision, i.e., decisions by MAC. Regarding MAC review of an ALJ decision, 42 U.S.C. § 405.1110(c)(2) provides:

> The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

Furthermore, when MAC reviews an ALJ decision, it conducts the review *de novo*. 42 C.F.R. §§ 405.100, 405, 1108(a). Lastly, when CMS did not participate in the proceedings below or appear as a party, MAC is explicitly authorized to correct errors of law committed below. *See* 42 C.F.R. 405.1110(c)(2).

In the CMS referral, the Secretary specifically alleges that "[t]he ALJ erred as a matter of law by failing to apply relevant CMS policies governing determinations of reasonableness and necessity. (CAR 38) (citing 42 C.F.R. § 405.1062(a)–(b)). In turn, MAC found that "the ALJ materially erred as a matter of law . . . [because] the ALJ did not consider or apply the applicable MPIM provisions for determining the medical reasonableness and necessity of the MOCA procedures." (CAR 16). Because Congress has authorized Medicare coverage only for those items and services medically reasonable and necessary, MAC was authorized to correct the ALJ's legal error in finding that the MOCA procedure was medically reasonable and necessary.

Plaintiff further argues that it was "sandbagged" because general medical reasonableness and necessity was not a ground for the original QIC decision, and this ground was therefore improperly considered in later appeals stages. (*See* ECF No. 24-1). Out the outset, this Court recognizes that a providers and suppliers bear the burden of maintaining and producing

information to support their payment of claims. *See* 42 C.F.R. § 424.5(a)(6). Additionally, 42 C.F.R. § 405.946 requires that parties requesting Redetermination "explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination." Furthermore, 42 C.F.R. § 405.966 provides, "When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the intitial determination, including the redetermination."

Here, Plaintiff was initially told that "Based on Medicare guidelines, the service(s) on the original claim was not considered medically necessary . . . based on either the documentation that was submitted or the failure by the physician/supplier to furnish information that was requested to support the claim." (CAR 25) (quoting contractor's Initial Determination denying the reimbursement claims)). Upon Redetermination, although the incorrect billing code and inapplicable LCD were considered, the decision focused largely on the lack of medical necessity and reasonableness of MOCA. *Id.* The Redetermination decision provided, "Sclerotherapy with injectable liquid or foam and compressions medically necessary for treatment of *small to medium-sized veins (3-6 mm in diameter)* . . . ." (CAR 1112) (emphasis added). On Reconsideration, the adverse decision provided, "The LCD determination that sclerotherapy is not considered effective for large veins greater than 6 mm diameter or the main saphenous veins, is valid in this instance. Based on the LCD's coverage exclusion and review of the medical records including treatment notes, the medical necessity of the procedures at issue is not demonstrated." (CAR 27). As argued by the Secretary, Plaintiff was on notice that it had not carried its burden regarding the medical necessity and reasonableness of MOCA well-before the ALJ hearings. MAC did not violate its

own regulations in deciding *de novo* an issue—medical reasonableness and necessity—that was present in this case since the initial determination.

"Respect for an administrative agency's implementation of its own regulations requires clear evidence to surmount the hurdle of arbitrary and capricious review. *Almy v. Selbius*, 679 F.3d 297, 309 (4th Cir. 2012). Having acknowledged that Plaintiff was on notice of the general finding against medical reasonableness and necessity, this Court finds "no reason to displace the presumption of regularity [that] attaches to the actions of government agencies.'" *Id.* (quoting *U.S. Postal Serv. V. Gregory*, 534 U.S. 1, 10 (2001)).

C. The Secretary's Final Administrative Decision is Legally Correct, Supported by Substantial Evidence, and not Arbitrary or Capricious.

Defendant asserts that "[i]t is *undisputed* that the final administrative decision under review is legally correct and supported by substantial evidence." (ECF No. 27, p. 1). Plaintiff rejects this claim and asserts, "[Plaintiff] disputes that the decision is legally correct on multiple bases." (ECF No. 30, p. 2). As explained above, this Court finds that collateral estoppel does not apply, and it finds that the Secretary did not violate his own regulations in reaching the final administrative decision. Plaintiff's filings focused solely on the legal issues of this case, so there has been no dispute that the decision by MAC is supported by substantial evidence.

Congress has excluded from Medicare coverage all items and services "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). "The Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Heckler*, 466 U.S. at 617 (citing *Kerr v. United States District Court*, 426 U.S. 394, 402–03 (1976)) (other citations omitted). Like Congress, the

Secretary's regulations exclude from Medicare all coverage and services that are not reasonable and necessary. 42 C.F.R. § 411.15(k)(1). In the absence of an applicable NCD or LCD, adjudicators must assess whether the "service is safe and effective, not experimental or investigational, and appropriate based on the strongest evidence possible." (CAR 16–17) (citing MPIM, Ch. 13 §§ 13.3, 13.5.1, 13.7.1)). An administrations interpretation of its own regulations "becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). "This broad deference is all the more warranted when, as here, the regulation concerns a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily requires significant expertise and entail the exercise of judgment grounded in policy concerns." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Therefore, this Court will provide the Secretary with the deference he is due in determining whether the MOCA procedures at issue were medically reasonable and necessary.

In his motion for summary judgment, Defendant outlines why MOCA was not considered medically reasonable or necessary on the dates relevant to this case. (ECF No. 18-1, p. 20–31). When a provider fails to produce evidence sufficient to demonstrate that treatment or services provided were medically reasonable and necessary, the Secretary is authorized to deny coverage. *See Almy*, 679 F.3d at 309. In *Almy*, the manufacturer of a device designed to treat osteoarthritis of the knee failed to produce credible evidence demonstrating the non-experimental nature of the device and that it was medically reasonable and necessary. *Id.* at 305. Finding that the plaintiff had not carried its burden of showing the medical reasonableness and necessity of the device at issue, the court in *Almy* held that "[t]hat there can be little doubt that the Secretary's decisions . . . are supported by substantial evidence." *Id.* at 307 (internal quotations omitted). Like the plaintiff in

Almy, Plaintiff here has not carried its burden of establishing MOCA as medically reasonable and necessary during the relevant periods. (*See* CAR 17) ("Here, despite the absence of an applicable NCD or LCD, the records do not include any published authoritative evidence, or support any general acceptance by the medical community, that the service was safe and effective, not experimental or investigational, and appropriate for the beneficiaries on the dates they received their MOCA procedures.")).

In its opinion, MAC recognizes that a "2017 draft version of the LCD explicitly described the procedure as experimental at that time, which was after the dates of service here." (CAR 17). "Specifically, while not dispositive because it was not in effect in 2014 and 2015, a medical review of the clinical studies and research available for this procedure result in the Draft LCD's conclusion that the endomechancial ablative approach . . . was at that time 'considered experimental, investigational, or unproven as substantial equivale therapy for varicose vein ablation.'" *Id.* Plaintiff has not provided sufficient evidence to support Medicare coverage for the MOCA procedures. *See Goodman v. Sullivan*, 891 F.2d 449 (2nd Cir. 1989) (Secretary denied coverage of MRI procedures before they were determined by Medicare to be safe and effective instead of experimental, investigative, and unproven).

In sum, giving the Secretary the deference required, this Court recognizes that the uncontested facts of this case indicate that the Secretary did not act arbitrarily and capriciously in reaching the final administrative decision, the Secretary adhered to the extensive administrative process he has set forth, and the decision was legally correct based on the certified administrative record.

IV. Conclusion

For the foregoing reasons, Defendant's Motion for Summary Judgment is GRANTED, Plaintiff's Cross-Motion for Summary Judgement is DENIED, Defendant's Motion for Leave to File Surreply is DENIED, and the final administrative decision of MAC is AFFIRMED.

Date: October 14, 2022

/s/
J. Mark Coulson
United States Magistrate Judge